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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,937	10/13/2004	Hubert Thoma	H-32407A	6977

1095 7590 08/15/2005

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
YEBASSA, DESTA LETTA	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,937	THOMA ET-AL.	
	Examiner	Art Unit	
	Desta L. Yebassa	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *SEP 08 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made for the oath or declaration filed on 10/13/2004. Receipt is also acknowledged of the information disclosure statement filed 09/08/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23-25, 27-29, 31-33, and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al. (WO 01/37808 A1).

Patel et al. teaches a wide variety of pharmaceutical active ingredients that includes hydrophilic, hydrophobic, lipophilic, amphiphilic, surfactants, etc. The solid pharmaceutical composition that includes a solid carrier, the substrate, and the solid carrier being formed of different combinations of pharmaceutical active ingredients (page 5, lines 15-25), an active ingredients can be any compound or mixture of compounds having therapeutic or other value when administrated to an animal, particularly to a mammal, such as drugs, nutrients, cosmeceuticals, diagnostic agents, nutritional agents, and the like (page 6, lines 10-150), suitable hydrophobic active ingredients such as anti-inflammatory agents, analgesics, anthelmintics, anti-bacterial agents, anti-viral agents, anti-fungal agents, anti-migraine agents, etc. (page 6, lines 30

and page 7, lines 5), suitable preferred hydrophobic active ingredients can be , for example, benazepril, albendazol, albuterol, amphetamine, etc. (page 8, lines 15-20 and page 9, lines 10). Patel et al. also teaches the substrate of the solid carrier compositions, which can be a powder or a multiparticulate, such as a tablet, a capsule, granul, a pellet, a bead, a microcapsule, a nanocapsule, a platlet. Such substrates can be formed of various materials for example sugars such as lactose, sucrose, dextrose, polysaccharides such as maltodextrin or dextrates, starches, cellulosics such as microcrystalline cellulose or hydroxymethyl cellulose etc (page 51, lines25 and page 52, lines 5). Furthermore, Patel et al. teaches surfactants such as anionic, cationic, non-ionic, and zwitterionic surfactants suitable for use in pharmaceutical compositions (page 16, lines 5); additives such as proteins and minerals suitable for use in pharmaceutical compositions (page 57, lines 15-25 and page 58, lines 15-25); preferred polymers such as shellac, acrylic polymer (methacrylic acid, cellulose derivatives (ethyl cellulose, methyl cellulose), polyvinyl polymer, etc. suitable for use in pharmaceutical compositions (page 62, lines 5-25 and page 63, lines 5-15). Patel et al. teaches the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (WO 01/37808 A1) in view of Lilley et al. (WO 01/35925 A1).

Patel et al. teaches a wide variety of pharmaceutical active ingredients that includes hydrophilic, hydrophobic, lipophilic, amphiphilic, surfactants, etc. The solid pharmaceutical composition that includes a solid carrier, the substrate, and the solid carrier being formed of different combinations of pharmaceutical active ingredients (page 5, lines 15-25), an active ingredients can be any compound or mixture of compounds having therapeutic or other value when administrated to an animal, particularly to a mammal, such as drugs, nutrients, cosmeceuticals, diagnostic agents, nutritional agents, and the like (page 6, lines 10-150), suitable hydrophobic active ingredients such as anti-inflammatory agents, analgesics, anthelmintics, anti-bacterial agents, anti-viral agents, anti-fungal agents, anti-migraine agents, etc. (page 6, lines 30 and page 7, lines 5), suitable preferred hydrophobic active ingredients can be , for example, benazepril, albendazol, albuterol, amphetamine, etc. (page 8, lines 15-20 and page 9, lines 10). Patel et al. also teaches the substrate of the solid carrier

compositions, which can be a powder or a multiparticulate, such as a tablet, a capsule, granul, a pellet, a bead, a microcapsule, a nanocapsule, a platlet. Such substrates can be formed of various materials for example sugars such as lactose, sucrose, dextrose, polysaccharides such as maltodextrin or dextrates, starches, cellulosics such as microcrystalline cellulose or hydroxymethyl cellulose etc (page 51, lines25 and page 52, lines 5). Furthermore, Patel et al. teaches surfactants such as anionic, cationic, non-ionic, and zwitterionic surfactants suitable for use in pharmaceutical compositions (page 16, lines 5); additives such as proteins and minerals suitable for use in pharmaceutical compositions (page 57, lines 15-25 and page 58, lines 15-25); preferred polymers such as shellac, acrylic polymer (methacrylic acid, cellulose derivatives (ethyl cellulose, methyl cellulose), polyvinyl polymer, etc. suitable for use in pharmaceutical compositions (page 62, lines 5-25 and page 63, lines 5-15). Patel et al. does not teach the typical food matrix ingredients that includes poultry meal; soya bean oil (fat, aid to processing); sugar (flavour, humectants); glycerol (softener, humectants); water (texture former, aid to processing); maltose glucose syrup (flavor humectants); salt (flavor, humectants); red iron oxide (mineral); milk, highly palatable etc. particular examples of medicaments such as agents that prevent or treat parasite infestations; components of vaccines; anti-flatulence agents; antibiotics; agents for the treatment of obesity; agents for the treatment of motor disorders; agents for the treatment of elevated blood pressure; anti- inflammatory agents; etc.

Lilley et al. teaches the food products that contains particles of a pharmaceutical agent, may be any material that is palatable, non-toxic, and easily ingestible, and preferably digestible by the animals, including liquid, semi-solid or solid in form, typically the food matrix will contain flours and starches and other materials necessary to aid processing, impart color, act as preservatives, impart texture and so on (page 4, lines 20-25), the typical food matrix ingredients are poultry meal (protein source, pliant); soya bean oil (fat, aid to processing); sugar (flavor, humectants); glycerol (softener, humectants); water (texture former, aid to processing); maltose glucose syrup (flavor humectants); salt (flavor, humectants); red iron oxide (mineral); milk, highly palatable etc. (page 4, lines 25-30 and page 5, lines 5-10). Lilley et al. also teaches particular examples of medicaments such as agents that prevent or treat parasite infestations; anti-worming agents; components of vaccines; anti-flatulence agents; antibiotics; agents for the treatment of obesity; agents for the treatment of motor disorders; agents for the treatment of elevated blood pressure; anti- inflammatory agents; etc. (page 5, lines 20-30). Lilley et al. does not teach a wide variety of pharmaceutical active ingredients that includes hydrophilic, hydrophobic, and their components, and the solid pharmaceutical composition that includes a solid carrier and formed from different combinations of pharmaceutical active ingredients.

The primary reference, Patel et al., teaches a wide variety of pharmaceutical active ingredients that includes hydrophobic, substrates, additives, polymeric materials and their typical examples used in pharmaceutical composition, and the solid

pharmaceutical composition that includes a solid carrier and formed from different combinations of pharmaceutical active ingredients as described above. The secondary reference, Lilley et al., teaches the typical food matrix ingredients that includes poultry meal; soya bean oil (fat, aid to processing); sugar (flavour, humectants); glycerol (softener, humectants); water (texture former, aid to processing); maltose glucose syrup (flavor humectants); salt (flavor, humectants); red iron oxide (mineral); milk, highly palatable etc. and particular examples of medicaments such as agents that prevent or treat parasite infestations; anti- inflammatory agents; antibiotics; components of vaccines; anti-flatulence agents; agents for the treatment of obesity; agents for the treatment of motor disorders; agents for the treatment of elevated blood pressure; as described above. The prior art references, as combined teach all the limitations.

It is the position of the examiner that the combinations of the prior art references recited are teaches all the limitation of the instant claims. Therefore, the invention as whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa
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Art Unit 1615

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